Approved Date: January 13, 2010
Revised Date(s): April 11, 2012
October 10, 2012

**CRITERIA FOR PRIOR AUTHORIZATION**

Tysabri® (natalizumab)

**PROVIDER GROUP:** Professional
**MANUAL GUIDELINES:** The following drug(s) requires prior authorization: natalizumab (Tysabri®)
**CRITERIA for Crohn's disease (CD):** (must meet all of the following)

- Patient must be 18 years of age or older
- Must be prescribed by a gastroenterologist
- Patient, Prescriber and Infusion Center must be registered with the CD Touch Program
- Patient must have a diagnosis of moderate to severe, active Crohn's Disease with evidence of inflammation
- Must have documentation of inadequate response to, or inability to tolerate, conventional Crohn's Disease therapies and TNF inhibitors
- Patient has not taken another biologic agent (see table) in the past 30 days
- Evaluation for latent tuberculosis infection with TB skin test prior to initial PA

**CRITERIA for Crohn's disease (CD) Renewal:** (must meet all of the initial PA criteria AND all of the following)

- Documentation of therapeutic benefit is required for renewal after initial three months of therapy
- Documentation of discontinuation of chronic steroid use (if applicable) is required for renewal after initial 6 months of therapy

**CRITERIA for multiple sclerosis (MS):** (must meet all of the following)

- Patient must be 18 years of age or older
- Must be prescribed by a neurologist
- Patient, Prescriber and Infusion Center must be registered with the MS Touch Program
- Patient must have a diagnosis of multiple sclerosis
- Must have documentation of inadequate response to, or unable to tolerate, an alternate multiple sclerosis therapy
- Patient is not taking an interferon, mitoxantrone, or fingolimod for MS.

**NOTE:** This drug carries a Black Box Warning: Progressive multifocal leukoencephalopathy (PML).

**Prior authorizations for multiple sclerosis may be approved for up to six (6) months.**

**The first two prior authorizations for Crohn's disease may be approved for up to three (3) months; all subsequent renewals may be approved for up to six (6) months.**

**Biologic Agents**

| Generic Name | Brand Name |
|---|---|
| Abatacept | Orencia® |
| Adalimumab | Humira® |
| Alefacept | Amevive® |
| Anakinra | Kineret® |
| Certolizumab | Cimzia® |
| Golimumab | Simponi® |
| Infliximab | Remicade® |
| Natalizumab | Tysabri® |
| Rituximab | Rituxan® |
| Tocilizumab | Actemra® |
| Ustekinumab | Stelara® |